

**BRS Stakeholder
Updates**

Sent by: Judy A Garrison

To:
cc:

Subject: APHIS Biotechnology Update 3

01/22/2004 03:57 PM

Dear BRS Stakeholder:

As the Animal and Plant Health Inspection Services' (APHIS) Biotechnology Regulatory Services (BRS) program enters another new year, we remain very aware that one of our foremost priorities is preparing for the challenges of a new and rapidly evolving industry. We're committed to meeting not only the challenges that we can see ahead on the horizon but also those that science has yet to discover. Synonymous with this commitment is our pledge to safeguard the environment and protect American agriculture. In keeping with these ideals, our last stakeholder update announced BRS' new Environmental and Ecological Analysis unit. Today, we announce plans to review and strengthen APHIS' current biotechnology regulations.

This exciting decision is the result of inter-agency discussions, which were led by the White House, and included our sister agencies, the Food and Drug Administration and the Environmental Protection Agency (EPA). We're now ready to take the first step and conduct an Environmental Impact Statement (EIS) to evaluate our biotechnology regulations. Notification of our intent will be published in Friday's Federal Register with a public comment period of 60 days.

The EIS, which will be conducted by APHIS, will evaluate environmental issues associated with potential revisions to existing regulations. APHIS has been regulating biotechnology since 1987, overseeing more than 10,000 genetically engineered (GE) crop field tests and deregulating 61 GE plant varieties. While APHIS' current regulations have been highly effective for ensuring the safe introduction of GE organisms since the 1980s, we're going to use this knowledge and expertise to determine how to best keep pace with the evolving demands of biotechnology.

Under the Plant Protection Act of 2000, APHIS has unprecedented authority to safeguard American agriculture and protect the environment. The EIS will look at expanding APHIS' regulatory scope beyond GE organisms that may pose a plant pest risk to include GE plants that may pose a noxious weed risk and GE organisms that could be used as biological control agents. APHIS recognizes that other Federal agencies also have authority to regulate GE organisms. For example, EPA has authority over certain biological control agents. This notice only addresses changes to APHIS regulations.

As part of the EIS, APHIS will evaluate the benefit of developing new criteria, based on risk, familiarity, and intended use (i.e. for pharmaceutical or industrial purposes), to review applications to conduct GE crop field tests. APHIS currently authorizes field testing under a system of both permits and notifications. Under the proposed approach, APHIS would move to a multi-tiered permitting system. This new system would utilize the knowledge we've gained about biotechnology in the last 16 years to help streamline the permit process for familiar field tests, so we can focus our resources and attention on new requests with which we have less

experience.

For example, a high degree of familiarity with crop biology, an introduced trait, or the interaction among the biology and the crop would lead to fewer permit conditions than a field test with a low degree of familiarity, which would call for a more cautious approach to confinement, oversight and monitoring. Over time, this science-based approach would reduce the regulatory burden and allow APHIS to concentrate oversight on new GE products with unfamiliar risks. Similarly, the EIS will consider how the concept of familiarity could be applied to other areas, including the importation of certain low-risk GE commodities.

The EIS will also consider the environmental effects of exempting, from regulation, the low-level and intermittent occurrence of certain GE organisms that have not completed all applicable review, provided they meet safety criteria and there has been adherence to regulatory requirements.

For more information on the scope of the EIS, please go to: <http://www.aphis.usda.gov>, click on APHIS Services and select “Search Regulations.”

Of all the exiting things we’re working on in BRS, for me, this is one of the most thrilling. We are at the beginning of a process to update our regulations, which will help us keep pace with the quickly changing science of biotechnology. Your input during this process will be critical to ensuring that we weigh all of our options and consider their potential impacts.

As part of our on-going efforts to make the regulatory process and its scientific basis more transparent, we plan to hold multiple public meetings as well as a scientific forum with key experts to discuss issues associated with the revised regulations. In an effort to solicit a wide range of view points, I also want to extend a personal invitation to any interested stakeholders who want to come to our offices in Riverdale, MD, and meet with BRS. We have set aside the week of Feb. 23 for this purpose. A summary of the meetings will become part of APHIS’ official administrative record. To set up a meeting, please call my office at (301) 734-7324.

Sincerely,

Cindy Smith
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service